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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/573,989  | 03/30/2006  | Heinz Von Der Kammer | 37998-237373        | 9161             |
| 26694 7590 09/16/2009<br>VENABLE LLP<br>P.O. BOX 34385<br>WASHINGTON, DC 20043-9998 |             |                      |                     |                  |
| EXAMINER  |             |                      |                     |                  |
| HIRIYANNA, KELAGINAMANE T   |             |                      |                     |                  |
| ART UNIT  |             | PAPER NUMBER         |                     |                  |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/573,989

**Applicant(s)**

VON DER KAMMER ET AL.

**Examiner**

KELAGINAMANE T. HIRIYANNA

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 11 December 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 11 and 12 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 11 & 12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/CDC)
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date: \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_
- Paper No(s)/Mail Date: \_\_\_\_\_

### DETAILED ACTION

Applicant's response filed on 12/11/2008 in response to office action mailed on 06/25/2008 has been acknowledged.

Claims 11 and 12 are amended.

Claims 1-11 and 13-30 were previously cancelled.

*Claims 11 and 12 are pending and are examined in this office action.*

*Applicants are required to follow Amendment Practice under revised 37 CFR §1.121. The fax phone numbers for the organization where this application or proceeding is assigned is 571-273-8300.* The Applicants arguments in the response filed on 12/11/2008 are fully considered while writing this action.

Applicants meets sequence compliance with respect to claimed SEQ ID NO:2 by appropriate corrections to previously submitted CRF in the response of 10/27/2008.

Withdrawn: Claims 11 and 12 rejections under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for the reasons of record as set forth in the office action mailed 06/25/2008 is withdrawn in view of Applicants appropriate amendments to the sequence nomenclature errors in the sequences/ CRF in the response of 10/27/2008.

Withdrawn: Claims 11 and 12 rejections under 35 U.S.C. 112, first paragraph for enablement for the reasons of record as set forth in the office action mailed 06/25/2008 is withdrawn in view of Applicants amendments to claims and appropriate amendments to the sequence nomenclature errors in the sequences/ CRF in the response of 10/27/2008.

Withdrawn: Claims 11 and 12 rejections under 35 USC 102 (b) as being anticipated by Farb et al., (WO 02/18541) for the reasons of record as set forth in the previous office action mailed on 06/25/2008 is withdrawn in view of Applicants amendments to claims and clarification to the sequence listing errors in the CRF and further in view of 35USC103 rejection as below.

**Claim Objections:**

Claims 11 & 12 are objected-to as the continue to use plural terms for e.g., "one or more substances" while referring to the single substance in step (i) i.e., "the protein molecule of SEQ ID NO:2". Appropriate corrections to the same are suggested.

**Claim Rejections - 35 USC § 103**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 11 & 12 are rejected under 35 USC 103 (a) as being unpatentable over Farb et al., (WO 02/18541; art of record) in view of Jakobovits et al (WO 0283921).

The above claims are directed to a method for screening for a modulator of Alzheimers associated with SULT4A1 gene, transcript, protein or derivatives and variants thereof by contacting a cell or animal with a test compound and measuring the alteration in the level of activity or said SULT4A1 or level of said SULT4A1 gene, transcript, protein or derivatives and variants thereof.

Regarding claims 11-12, Farb teaches method of screening for identifying an effector (modulator) of nervous system-specific sulfonation by SUL<sup>Tn</sup> (which is same as SULT4A1 enzyme) (p.40-41). Farb's method comprises contacting under physiological conditions (cells and animals) wherein Farb's compound is a peptide, a nucleic acid, a antibody or an organic or an inorganic molecule (p.41, lines 17-24). Farb further teaches that SUL<sup>Tn</sup> (SULT4A1) may be associated with a neurological disorder such as schizophrenia, Alzheimer's disease (p.40-41) etc., and the gene for SULT4A1 maps at chromosome 22q13 that encompasses schizophrenia-susceptibility locus (Abstract, p.28). Further Farb reference clearly teaches method of treating (modulating) Alzheimers disease comprising administering SULT4A1 polypeptide (modulator). The said modulator increases the sulfotransferase activity when provided to a cell (p.41, paragraphs 2-3). Further Farb clearly teaches method of measuring SULT4A1 sulfotransferase enzyme and its expression by its ability to bind PAP-Agarose and by its activity to form sulfate groups

on small neuro-chemicals (p.4, lines 1-27). Farb however, does not teach SULT4A1 with a 100% sequence identity to SEQ ID NO:2

At the time of invention Jakobovits, teaches polypeptides encoding polynucleotides that possess 100% sequence identity to instantly claimed SEQ ID NO:2 (see attached STIC sequence search file: 10573989 STIC.pdf Pages 3 of 3) and teaches substances that modulate these proteins and polypeptides and their usefulness in diagnostic , prognostic or therapeutic purposes (entire article; abstract; search summary)

Thus it would have been obvious for one of ordinary skill in the art to substitute SULTn (a SULT4A1 family member) of the Farbs method of screening modulators of Alzheimers, with Jacobovits polypeptide/polynucleotide sequences that is a closely related member of the SULT4A1 (sulfotransferase) family (i.e., 100% identical to SEQ ID NO:2 of instant invention) to screen for the Alzheimers disease modulators. . One of ordinary skill in the art would have been motivated to make and use a SULT4A1 (with 100% identical to SEQ ID NO:2) as it is structurally closely related to the SULTn, the well known in the art to be associated with neurodegenerative diseases including Alzheimers.. One of ordinary skill in the art would "try" and would be expected to have a reasonable expectation of success of making and using a SULT4A1 family member that is structural homology or sequence identity to the art established SULTn sulfotransferase for screening for the modulators of Alzheimers disease. Thus, the claimed invention was *prima facie* obvious.

#### **Response to Applicants Arguments of 12/11/2008:**

The Applicant argues that the '541 publication does not anticipate the claim since it does not teach SEQ ID NO:2 and hence the Applicants requests that the rejection be withdrawn.

The Applicants arguments are however, found not persuasive because, the previous rejections of anticipation under 35 USC 102 was based on non availability of the sequence data for SEQ ID NO: 1 or 2. However, since the Applicant has currently corrected the sequence listing in the response of 12/11/2008, a prior art sequence search for claimed SEQ ID NO:2 was conducted (a copy of search has been provided herewith for Applicants reference). Prior art search indicates that SEQ ID NO:2 has been

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described prior to instant invention thus making the invention as claimed obvious. Hence a rejection of obviousness under 35 USC 103 (a) has been promulgated as above.

***Conclusion:***

No claim allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner *Kelaginamane Hiriyanna Ph.D.*, whose telephone number is **(571) 272-3307**. The examiner can normally be reached Monday through Thursday from 9 AM-7PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *Joseph Weitach Ph.D.*, may be reached at **(571) 272-0739**. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). When calling please have your application serial number or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. For all other customer support, please call the USPTO call center (UCC) at (800) 786-9199.

/Robert M Kelly/  
Primary Examiner, Art Unit 1633